Philip Morris, USA Pilot Total Exposure Study Proposed Timeline (Continued)

| Study No. | 8450 | | |
|--|-------------|----------------------|----------------------|
| The second secon | Contact | Projected Date | Actual Date |
| CRF comments to CRU | J. Oey | 04/09/01 | 04/09/01 |
| Submit Protocol, Questionnaire, | M. Larson | 04/04/01 | 04/04/01 |
| Diary, and Informed Consent to IRB | | (Informed Consent) | (Informed Consent) |
| | | 04/18/01 | 04/18/01 |
| | | (Protocol/ | (Protocol/ |
| | | Questionnaire/Diary) | Questionnaire/Diary) |
| IRB Meeting | M. Larson | 04/09/01 | 04/09/01 |
| | | (Informed Consent) | (Informed Consent) |
| | | 04/23/01 | 04/23/01 |
| | : | (Protocol/ | (Protocol/ |
| | | Questionnaire/Diary) | Questionnaire/Diary) |
| Draft Data Management Plan to | R. Chaouki | 04/27/01 | 04/27/01 |
| Philip Morris | | | |
| 2 nd Draft RAP to Philip Morris | R. Chaouki | 05/02/01 | 05/02/01 |
| Study Initiation | M. Larson | 05/01/01 | 05/01/01 |
| Draft Data Management Plan Comments to CRU | J. Oey | 05/04/01 | 05/04/01 |
| 2 nd Draft RAP Comments to CRU | B. Nelson | 05/23/01 | 05/23/01 |
| LVO | M. Larson | 06/18/01 | 06/18/01 |
| Finalize RAP | R. Chaouki | 08/03/01 | 08/07/01 |
| Analytical Method Validation Complete | K. Phillips | 08/24/01 | |
| Source Document Info. Transferred to CRFs | M. Larson | 07/23/01 | 07/23/01 |
| CRFs Delivered to Data Management | M. Larson | 08/06/01 | 07/27/01 |
| CRFs Entered into Data Base | R. Chaouki | 08/16/01 | |
| CRF Edit Checks Completed | R. Chaouki | 08/30/01 | |
| Bioanalytical Data Available | K. Phillips | 12/03/01 | |
| CRF Queries Resolved | M. Larson | 10/05/01 | |
| Bioanalytical Reports | K. Phillips | 12/05/01 | |
| Data Base Lock | R. Chaouki | 02/22/02 | |
| Draft CTR | T. Janisch | 02/28/02 | |
| Final CTR | T. Janisch | 04/25/02 | |

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